

Minutes of TES Weekly Status Meeting (PM-8451)

May 19, 2003

Page 1 of 2

Participants

Philip Morris

Valerie King

Robin Kinser

Bettie Nelson

Jan Oey

Hans-Juergen Roethig

Mohamadi Sarkar

MDS

Kim Prchal

Art Singer

Steven Zweig

Covance

Lisa Geishirt

Eric Larson

Jill Schultz

Mary Westrick

The following items were discussed:

Approval of 05/12/03 Minutes

Minutes from 05/12/03 were approved with no changes. A spelling error was noted for Tulane.

Call Center Information

There are a total of 195 future appointments. Hans questioned why the CRU did not have any appointments scheduled. Lisa indicated that there were no subjects that called as a result of the direct mailing for the CRU that qualified. Only 39 subjects have been recruited as a result of the direct mailing. Many subjects do not qualify because they smoke multiple brands. Hans suggested that the inclusion criteria be changed to include subjects that smoked the same brand for 4 weeks rather than 3 months. Eric Larson indicated that the questionnaire includes questions regarding the 3-month inclusion criteria. Philip Morris agreed that it would be best to keep the inclusion criteria as is. Mary Westrick and Lisa Geishirt indicated that additional advertising might be the best way to recruit additional subjects rather than another direct mail. Philip Morris approved that the funds designated for the direct mailing should be used for additional advertising.

ACTION: M. Larson to notify sites.

PM3001194445

Minutes of TES Weekly Status Meeting (PM-8451) - Continued

May 19, 2003

Page 2 of 2

Stratification Cells

Enrollment is at 3,779. New evaluation by Philip Morris shows that chances are pretty good for hitting target enrollment. Even with enrollment at 396 for tar group 1, the statistical power is 85%. Philip Morris asked about adding additional sites. Mary Westrick indicated that this could take 3 to 4 months. The supply of topography devices may also be an issue.

Site Performance Markers

Eric Larson is investigating the low number of topography downloads. He indicated that some sites have issues with logging in or the repair program. He has contacted several sites to resolve the issues and the no. of files downloaded should increase.

ACTION: J. Schultz/E. Larson to continue to monitor no. of downloads.

Topography Data Cleaning

Options on how to handle this are still being discussed within Philip Morris.

ACTION: J. Schultz to include on next week's agenda.

TES Time Line

Philip Morris indicated that the timeline for 11-dehydro and 8-epi-prostaglandin is fine as is. Mark Bentley has indicated that the nicotine and metabolite assays have fallen behind due to instrumentation problems but that the projected end date should not change. The ABP analyses for the TES have moved out a week due analyses for another study being added.

Data can now be sent to MDS. Steven Zweig indicated that he would be contacting Toyna Funk at CCLS to discuss data transfers. **ACTION: J. Schultz to notify team to begin data transfers.**

Statistical Analysis Plan

MDS and Philip Morris will be meeting the end of May to discuss SAP,

Follow Up Study

Philip Morris is still discussing the design. Should have more information by the end of May.

Next Call

Date: June 2, 2003

Time: 1:00 pm CT/2:00 pm ET

Password: CCS

Conference Leader: Jill Schultz

Toll Free No.: 888-384-8977 (domestic)

484/630-7995 (international, if needed)

PM3001194446